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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,421	06/11/1999	JOHN FRANCIS GORDON	043601/0110	2286

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Donald Bollella, Esq.  
Chief Patent Counsel BURSTEIN TECHNOLOGIES, INC.  
163 Technology Drive  
Suite 200  
Irvine, CA 92618

EXAMINER

WALLENHORST, MAUREEN

ART UNIT PAPER NUMBER

1743

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/284,421

Applicant(s)

GORDON, JOHN FRANCIS

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 89-99, 105-131 and 141-155 is/are pending in the application.
- 4a) Of the above claim(s) 141-155 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 89-99 and 105-131 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. Applicant is notified that the Examiner of this application is now Examiner Maureen Wallenhorst. Applicant is also notified that withdrawn claims 141-155 were not cancelled in the response received on August 23, 2004, and therefore, these claims are still pending, but not examined since they are directed to a non-elected invention.
2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
3. The abstract of the disclosure is objected to because the abstract from the corresponding PCT application should be put on a separate sheet. Correction is required. See MPEP § 608.01(b).
4. Claims 93-99 and 105-131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 93, the phrase "the multi-well structure" lacks antecedent basis since independent claim 89 does not positively recite wells in the assay plate, only reaction sites. It is suggested to rewrite claim 93 to read: --The assay plate structure of claim 89 wherein the structure includes upper and lower circular plates, ...--.

On line 2 of claim 95, the phrase "the upper and lower plates" lacks antecedent basis since independent claim 89 recites "upper and lower surfaces". See this same problem in claims 96-97.

Claim 98 is indefinite since it is redundant with independent claim 89. Both claims 89 and 98 recite that the structure is a disc. See this same problem with claims 105 and 112.

On line 2 of claim 99, the phrase "said wells" lacks antecedent basis.

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Claim 105 is indefinite since on line 10, the word "enclosed" is misspelled.

On line 2 of claim 119, the phrase "said one or more inserts" lacks antecedent basis since claim 119 depends from claim 118, and claim 118 does not positively recite inserts.

On line 8 of claim 123, the phrase "said opening" lacks antecedent basis.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 89-94, 96-99, 105-113, 116, 121-127 and 129-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (WO 96/09548) in view of Croteau et al (applied in the last Office action mailed on May 20, 2003).

Gordon teaches of an apparatus for conducting the optical inspection of a biological, chemical or biochemical sample supported on an optically transparent disc. The apparatus comprises a substrate having a surface for supporting a sample, a source of electromagnetic radiation for providing a beam of electromagnetic radiation, a means for scanning the beam across the surface of the substrate, and a detector means arranged to detect electromagnetic

radiation reflected and/or transmitted through the substrate, wherein the substrate is provided with digitally encoded information thereon that is scanned by the beam of electromagnetic radiation and that contains information indicative of the address or location on the surface of the substrate which the beam is currently directed. The detector means is arranged to decode the electromagnetic radiation beam to determine the encoded address and to determine if the received beam has been modulated by any of the sample on the substrate. The provision of address information in or on the substrate enables the precise position of the electromagnetic radiation beam on the surface to be determined which in turn allows the accurate mapping of optical data, corresponding to attached material, on the surface. The substrate is provided in the form of a circular disc 1 that has a surface for supporting a sample and a surface with a plurality of perturbations that represent the digitally encoded data. The disc 1 comprises upper and lower layers of transparent plastic 2, 3, with a reflective layer sandwiched in-between. A lens arrangement 10 is located on the disc structure. In the embodiment depicted in Figure 6 of Gordon, the disc 44 comprises a plurality of wells or indentations 51 formed in its upper surface. The wells contain different samples to be inspected. Gordon also teaches that it is possible to construct the disc in such a way that the support surface is internal to the disc and is not the upper surface of the disc. This provides the advantages that the sample is not damaged by handling and that a precise volume of sample is analyzed. See pages 3-4, 7, 10, 12, 14 and 22-23 of Gordon. Gordon qualifies as a reference under 35 USC 102(b) since it was published on March 28, 1996, which is more than one year from the effective filing date of the instant application (i.e. August 10, 1997). Gordon fails to teach that the disc has an upper surface and a lower opposed surface with a space there between with reaction sites on the lower surface and an

opening in the disc for allowing a sample liquid to be introduced into the space by capillary action between the upper and lower surfaces.

Croteau et al teach of a multi-well assay disc plate 10 comprising a lid, a second lower surface having a plurality of wells 12 disposed therein, wherein the lid and second surface define a chamber having an opening 24 therein which allows fluids to be introduced and withdrawn from the chamber. The plate is made from a hydrophobic material. Moreover, each well is adapted to hold an aliquot of liquid and is sized and shaped and formed of a suitable material to hold the aliquot with the well by surface tension. Additionally, the surface of the wells can be treated with a hydrophilic material to enhance the retention of the liquid in the wells. See column 2, lines 43-45, column 4, line 52-column 6, line 60 and Figures 2A-4B in Croteau et al.

Based upon the combination of Gordon and Croteau et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide the disc taught by Gordon with upper and lower closely spaced surfaces with a space there between having an opening for introducing and removing sample liquids, similar to the configuration of the assay device taught by Croteau et al, in order to protect the reaction sites on the disc from contamination present in the environment, especially in light of the suggestion by Gordon that the disc may be constructed so that the reaction sites are internal to the disc to provide the advantages that the sample is not damaged by handling and that a precise volume of sample is analyzed.

8. Claims 95, 114-115, 117-120 and 128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon in view of Croteau et al as applied to claims 89-94, 96-99, 105-113, 116, 121-127 and 129-131 above, and further in view of Merkh et al (applied in the last Office

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action mailed on May 20, 2003). For a teaching of Gordon and Croteau et al, see previous paragraphs in this Office action. Gordon fails to teach that the disc assay plate is subdivided into removable sectors by dividing walls.

Merkh et al teach of a disc structure 18, which is divided into sector inserts 80 comprising wells 84. The system of Merkh et al includes a liquid injecting device 31, which penetrates the self-sealing cover 90 of each sector at port 92 (see column 10, lines 1-7). The sector inserts 80 and the disc 18 include locks 100, 102, 104 and key 93 portions to allow the sectors to be snap-fitted in the correct orientation on the disc 18. Additionally, the disc comprises a plurality of dividing walls 131.

Based upon the combination of Gordon, Croteau et al, and Merkh et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to subdivide the disc assay plate taught by Gordon into removable sectors separated from one another by dividing walls, similar to the configuration of the disc plate taught by Merkh et al, so as to provide means for analyzing a plurality of samples applied to the different sectors at the same time while keeping the samples separated from one another to avoid contamination, thus allowing more tests to be run in a given amount of time.

9. Applicant's arguments with respect to claims 89-99 and 105-131 have been considered but are moot in view of the new ground(s) of rejection.

The previous rejections of the claims made under 35 USC 112, first paragraph and under 35 USC 103 in the last Office action mailed on May 20, 2003 have all been withdrawn in favor of the new rejections set forth herein. Therefore, Applicant's arguments concerning these previous rejections will not be addressed. This Office action is non-final.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

November 29, 2004

*Maureen M. Wallenhorst*  
MAUREEN M. WALLENHORST  
PRIMARY EXAMINER  
GROUP 1000 1700